Attorney Docket No.: 05033.0002.CPUS02

Application No.: 10/650,057

In the Claims:

1. (original) A method for detecting cervical carcinomas, cervical intraepithelial neoplasias or cervical carcinomas in situ from a solubilized sample of a human subject in a human

subject, the method comprises the steps of:

(a) obtaining a cervical body sample from [[a]] the human subject,

(b) solubilizing the cervical body sample in a lysis buffer, and

(c) reacting the solubilized cervical sample in the lysis buffer with an antibody

against cyclin dependent kinase inhibitor p16, and

(d) determining the overexpression of cyclin dependent kinase inhibitor p16 in the

solubilized cervical sample by comparing the level of cyclin dependent kinase inhibitor p16

within said solubilized cervical sample with the level present in a solubilized healthy human

cervical sample.

2. (original) The method according to Claim 1, wherein the level of cyclin dependent kinase

inhibitor p16 in the healthy human cervical body sample is provided as a predetermined

value to set up a threshold for the detection procedure.

3. (original) The method according to Claim 1, wherein the level of cyclin dependent kinase

inhibitor p16 in a healthy human cervical sample is determined from a standardized

sample solution, or from a representative number of healthy human cervical samples.

4. (original) The method according to Claim 3, and wherein the determination of the level of

cyclin dependent kinase inhibitor p16 in a healthy human cervical sample is carried out:

a. in the course of the detection procedure,

b. upon calibration of the detection system,

c. once for each lot of detection reagents, or

d. as a standard value for the detection method.

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5. (original) The method according to Claim 1, wherein the cervical body sample is swab, smear, aspirate, biopsy, preserved cytological specimen, histological specimen, fixed cell preparation or fixed tissue preparation.

- 6. (original) The method according to Claim 1, wherein the cervical body sample is solubilized
 - a. immediately after obtaining the sample,
 - b. after storage and/or transport in a storage buffer, or
 - c. after transport in a transportation buffer.

7-18. (Cancelled)

- 19. (New) The method according to Claim 1, wherein the lysis buffer comprises at least one composition selected from the group consisting of chaotropic agents, anionic detergents, cationic detergents, non-ionic detergents, amphoteric detergents, and alkaline compositions.
- 20. (New) The method according to Claim 19, wherein the lysis buffer comprises an anionic detergent and a non-ionic detergent.
- 21. (New) The method according to Claim 20, wherein the lysis buffer further comprises a proteinase inhibitor.
- 22. (New) The method according to Claim 20, wherein the anionic detergent is SDS.
- 23. (New) The method according to Claim 1, wherein the overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample is determined by an ELISA.
- 24. (New) The method according to Claim 1, wherein the overexpression of cyclin dependent kinase inhibitor p16 in the solubilized cervical sample is determined by a lateral flow assay.